SIEMENS

Surgery Products

SP

Update Instructions SP022/05/S

Title: Fixation of the laser diode output windows

Reason for update:	☒ Safety		
Urgency:	☐ Immediate	☒ Within	3 months
Materials for classic update handling required?	☒ Yes	☐ No	
Remote update handling feasible?	☐ Yes without CSE	☐ Yes, with CSE	☒ No
File download available?	☐ Yes	☒ No	
Materials free of charge?	☒ Yes	☐ No	
Return of parts?	☐ Yes	☒ No	
Estimated completion time:	1/2 hour	Number of CSE's: 1	
Customer application training?	☐ Yes	☒ No	

Systems/Products affected / System identifying IVK

Name	Material No.	Serial No.
ARCOSKOP, POWERMOBIL, SIREMOBIL Compact, , SIREMOBI Compact L, SIREMOBIL Iso-C, ARCADIS Varic, ARCADIS Orbic	4774019, 2830011, 3776494, 3780629, 2829450, 8080017, 8081080	All systems equipped with Laser light localizer

Components affected / to be modified / IVK

Name	Material No.	Serial No.	Component status affected
Laser light localizer	30 99 988	*2000 to *2521, *2523 to *2530, *2535, *2539, *2541 to *2544, *2551	n.a.

Remark:

Chg. Ref. No.: 146002
Name: Arnold
Dept.: CS PS 24

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Document Revision Level

This document corresponds to the version/revision level effective at the time of system delivery. Revisions to hardcopy documentation are not automatically distributed.

Please contact your local Siemens office to order current revision levels.

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Components affected

Laser light localizer 30 99 988 from Serial No.
*2000 to *2521, *2523 to *2530, *2535, *2539, *2541 to *2544, *2551.

Comments: The asterisk * is used as placeholder for the letter S or the number 0.

Systems / Products affected

The Laser light localizer was / is available for the following systems:

ARCOSKOP	Part No. :	4774019	Serial No.:	n.a.
SIREMOBIL Compact	Part No. :	3776494	Serial No.:	n.a.
SIREMOBIL Compact L	Part No. :	3780629	Serial No.:	n.a.
SIREMOBIL Iso-C	Part No. :	2829450	Serial No.:	n.a.
POWERMOBIL	Part No. :	2830011	Serial No.:	n.a.
ARCADIS Varic	Part No. :	8080017	Serial No.:	n.a.
ARCADIS Orbic	Part No. :	8081080	Serial No.:	n.a.

Reason for the Update

The screws fixing the laser diode output windows can become loose.

Special Tools / Documents

- Standard tool kit
- 1 set of Allen keys
- Thread locker LOCTITE 243, Part No. 55 07 038
- or similar (medium strength, can be released)
- System binder of the product concerned.

Ordering Information

The following update kit has to be ordered from CSML (SAP Distribution Channel, factory 2050) or BU Logistics (factory BU) (only with an order via BU Logistics):

Laser light localizer update kit **Material no. 71 41 117**

Contents of the Update Kit

Update kit **71 41 117** contains the following parts:

Pos.	Quan.	Material No.	Name
1	8	n.a.	Allen screws 1.6 mm x 6 mm
2	1	n.a.	Allen key 1.6 mm
3	1	SP00-000.896.05.01.02	Update instructions

Tab. 1

Return of Parts

n.a.

Safety Informations

⚠WARNING

Danger of possibly fatal physical injury and property damage!
Observe

- **the product-specific safety information in the service instruction of the system concerned,**
- **the general safety information in instructions TD00-000.860.01... and**
- **the general safety information according to ARTD Part 2.**

Noncompliance can lead to death, physical injury or property damage.

⚠WARNING

Danger of infection with pathogens!
Noncompliance can lead to death or physical injury.

Since the system concerned has been approved for use in operating rooms, it may be contaminated with infectious blood or other excreta.
Avoid any skin contact with blood or other excreta!
The preventive measures against infectious diseases specified in ARTD-002.731.37... must be strictly observed at all times!

Prerequisites

Before starting the work steps, check laser light localizer for mechanical damages.

- Check the On / Off switches. Both switches must activate / deactivate the laser beams.
- After switching on, both laser beams must be visible.
- The laser beams must be switched off automatically after approx. 1 minute.
- Install the laser light localizer on the I.I. of the system. With the knurled screws on the laser diode housings, the laser beams must be adjustable to the geometrical center of the SIREPHOS (red Focus spot) / POWERPHOS (center of the plexiglass window).

If the laser light localizer is damaged or defect, inform the customer.

NOTE	**Perform the work steps, described on the next pages also, if the laser light localizer is defective and must be repaired or changed!**

Work steps

Fig. 1 Laser light localizer 30 99 988 Top view

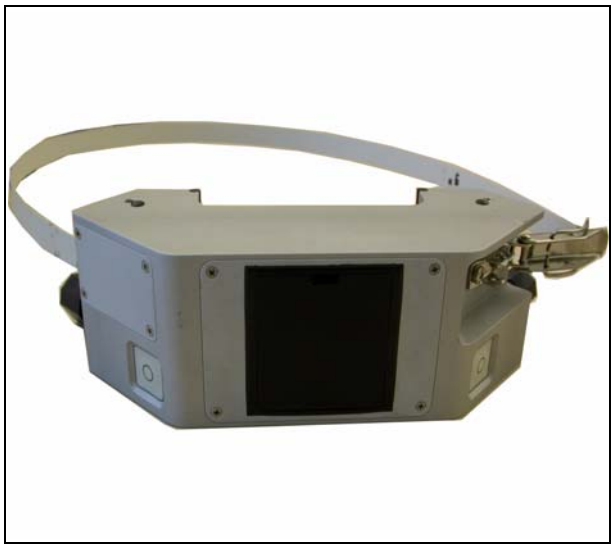

Fig. 2 Laser light localizer Front view

Fig. 1 and Fig. 2 show the laser light localizer.

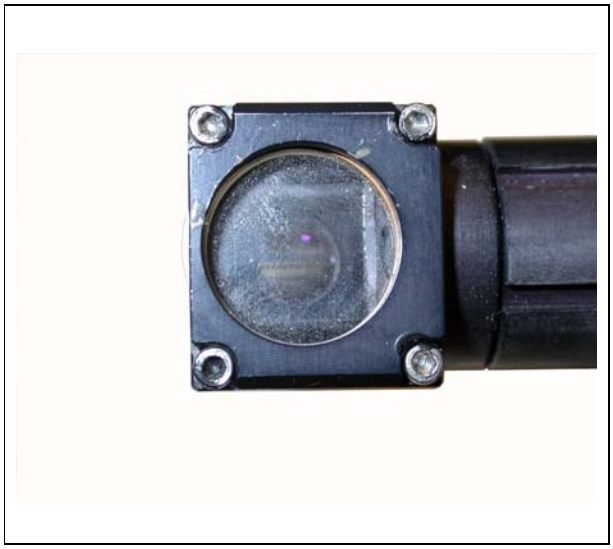

Fig. 3 Laser light localizer Output window

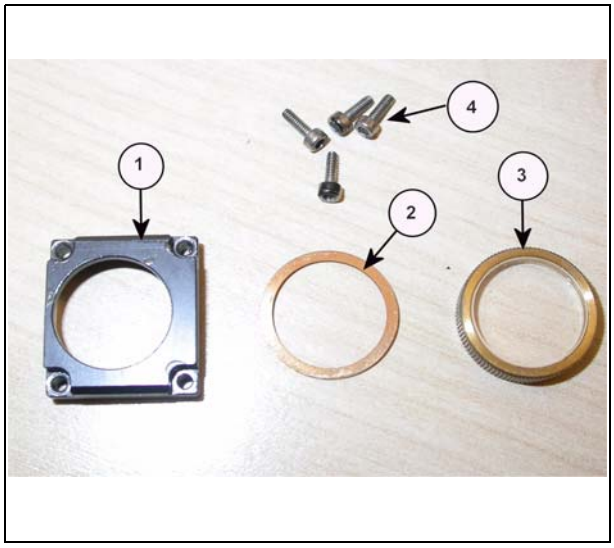

Fig. 4 Laser light localizer Output window Individual parts

Cleaning the Output windows

- Loosen the 4 Allen screws of the laser diode output window (Fig. 3).
  The output window includes the metal holder 1 / Fig. 4, the washer 2 / Fig. 4 and the prism 3 / Fig. 4.
- Carefully take out the prism (3 / Fig. 4) and the washer (2 / Fig. 4) from the metal holder (1 / Fig. 4).
- Carefully clean the metal holder, the washer and the prism under warm water and - if available with household cleaning agent (dishwashing liquid). **Don't use cleaning agents containing abrasives.**
- Clean the knurl (outer ring) of the prism.

- Carefully dry the prism, washer and metal holder using a dust free towel.

Fig. 5 Laser light localizer Holder with inserted washer

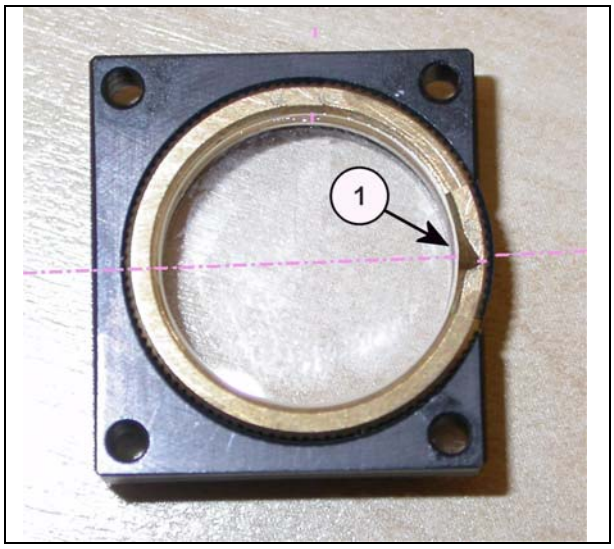

Fig. 6 Laser light localizer Holder complete

- Carefully insert the washer in the metal holder (Fig. 5).
- Carefully insert the prism into the metal holder (Fig. 6).
- Take care that the groove (1 / Fig 6) in the metal ring of the prism is visible and in the position shown.

NOTE

First check that the prism can be rotated with normal force before applying the thread locker to the screws.

- Temporarily fasten the output window (metal holder with washer and prism) at the laser diode.
- Check that the prism can be rotated with normal force.

NOTE

If the prism sticks and cannot be rotated, remove the output window again, remove the prism and washer and check that the parts are clean.
The washer is slightly bent. Lay it on a table and press it flat using an Allen key.
Carefully insert the washer and prism in the holder.
Take care that the groove is visible and in the position 1 / Fig. 6.
Fasten the output window again and check that the prism can be rotated with normal force.

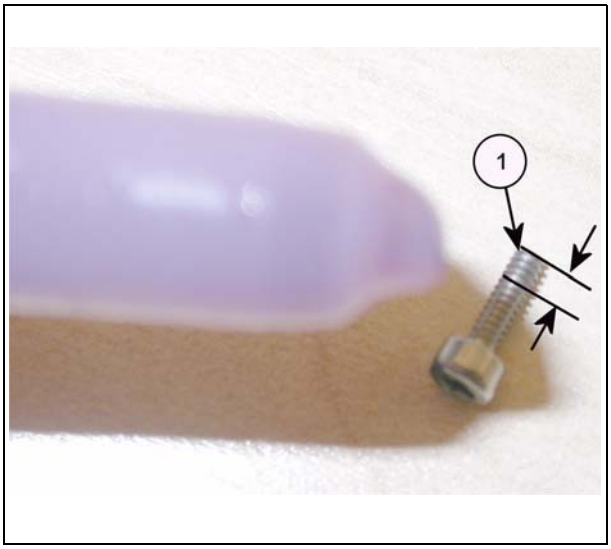

Fig. 7 Laser light localizer Applying thread locker

Securing the fixing screws of the output windows

- Remove the screws from the output window again.
- Apply the thread locker, type Loctite 243, to the thread (1 / Fig. 7).
  The thread locker should be applied in the place between the lines, as shown in Fig. 7.

NOTE	**The metal ring of the prism 3 / Fig. 4 should not come in contact with the thread locker to prevent it from sticking to the metal holder 1 / Fig. 4.**

Final Check

Check all other screws that these are present and tightened.

Check the function of the laser light localizer.

Customer Information

NOTE	**Only necessary if the laser light localizer could not be updated for any reason.**

- If the laser light localizer could not be updated, inform the customer
  that the 8 screws fixing the output windows of the laser diodes (see Fig. 3)
  need to be secured using a thread locker to prevent them from loosening and falling off.
- Fill out the form sheet (page 9).
  Send it to the address printed on the rear side of the form sheet (page 10).
- Insert these update instructions into the system binder / Log book.

Final Work Steps

- Updates that have already been completed prior to publication of this SI must also be reported.
- The update is reported as follows:
  The modification reply report has to be prepared by authorized personnel using an application on the Intranet.)

Changes to Previous Version

n.a.

Confirmation Letter

Complete and send this confirmation letter to the specified address (see page 10), only if the laser light localizer 30 99 988 concerned could not be updated.

(mark the accordingly check boxes).

Material: Laser Light Localizer Material number: 30 99 988

Serial number: .....

Customer: ..... Functional Location: .....

Customer No.: .....

☐ The Update instructions SP022/05/S could not be performed.

Reason (short description):_____

_____

_____

☐ The Customer was informed that the Laser light localizer needs to be updated. The 8 screws fixing the output windows of the laser diodes (see Fig. 3 of this UI) need to be secured using a thread locker to prevent them from loosening and falling off.

Name (CSE): ..... Telephone: .....

Country: ..... Location: .....

Date: ..... Signature: .....

Remark: .....

.....

Please send the Confirmation letter (only page 9) via fax to:

SIEMENS Medical Solutions
Germany
attn. Mr. Dr. Trautner
Dep. SP QM
Henkestrasse 127
91052 Erlangen
Germany

Fax (foreign Countries): (+49) 91 31 84 87 50
Fax (Germany): 09131 84 87 50

Completion Protocol

(Not required for "Remote updates without a service technician")

The update with the number **SP022/05/S** has been completed.

Material number: .....

Serial number: .....

Customer: ..... Functional Location: .....

Customer No.: .....

Name (CSE): ..... Telephone: .....

Country: ..... Location: .....

Date: ..... Signature: .....

Remark: .....

.....

NOTE

After completing the update, make a copy of this page, fill it out and file it in the corresponding System Binder/User Handbook.

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